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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/501,217	02/10/2000	Howard Murad	2267-017	3548

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PENNIE & EDMONDS LLP  
1667 K STREET NW  
SUITE 1000  
WASHINGTON, DC 20006

EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 09/09/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/501,217

Applicant(s)

MURAD, HOWARD

Examiner

Lakshmi S Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-9,11-23 and 25-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1,2,4-9,11-23 and 25-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### **DETAILED ACTION**

Receipt of amendment D dated 6-18-02 is acknowledged.

Claim 24 has been cancelled. New claims 28-30 are added. Claims 1, 2, 4-9, 11-23 and 25-30 are pending.

#### ***Response to Arguments***

Applicant's arguments with respect to claims 1, 2, 4-9, 11-23 and 25-30 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Claim Objections***

1. Examiner notes that the marked up version of amended claims underline only tannic acid in claim 1. However, instant amendment incorporated both tannic acid and manganese in claim 1. Claim 1 was previously amended (paper #9, amendment B) to delete manganese, copper and selenium components and only retained cysteine component.

#### ***Claim Rejections - 35 USC § 112***

2. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "mono- or poly-hydroxy acid or tannic acid", which is indefinite because in claim 3 applicants recite tannic acid as one mono- or poly-hydroxy acid. Therefore, it is not clear from the instant expression "mono- or poly-hydroxy acids or tannic acid", if tannic acid of claim 1 is the same as that of claim 3 or is it different. A clarification and appropriate correction is requested.

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3. Claims 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants cancelled claim 24 in response to previous action (paper #10). However, applicants failed to cancel claims 25-27, which depend from the canceled claim 24. It is unclear to the examiner if applicants intend to make claims 25, 26 and 27 depend on any other independent claim. It is indefinite and confusing as to what are the meets and bounds of claims 25-27. A clarification and appropriate correction is requested.

***Double Patenting***

4. Claims 1, 2, 4-9, 11-23 and 25-30 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Application no. 09/501,218. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims recite a method of managing dermatological conditions comprising administering a composition that reads on the instant composition. Instant claims also recite the same utility as of the copending claims. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ the composition used in the copending method for the claimed utility of the instant invention i.e., for managing a dermatological condition.

**Applicants stated in their response that this rejection, which has been previously made, would be addresses when either the present or the co-pending application is allowed. Accordingly, the rejection is maintained.**

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***Claim Rejections - 35 USC § 103***

5. Claims 1, 2, 4-9, 11-23 and 28-30 rejected under 35 U.S.C. 103(a) as being unpatentable over Lansky in view of Crotty et al and Thornfeldt et al.

Lansky teaches pomegranate extracts in topical composition for supplementing phytoestrogens. Lansky teaches extracting pomegranate seeds and admixing with other herbal extracts such as licorice (col. 4), adding carriers such as beeswax, cocoa butter, citric acid (col. 6, lines 37-38 and 61) and using the composition as a skin cream (abstract, col. 2, lines 3-36) for treating oily skin (col. 2, lines 20-23). The phytoestrogens of schizandra berries (col. 4, lines 1-3) read on other antioxidant of instant claim 20. Lansky teaches topical as well as oral administration of phytoestrogens. Lansky fails to teach pomegranate extract in an amount sufficient to neutralize free radicals. However, claim 2 recites teaches the amount as 0.01 to 80 weight percent and Lansky teaches 1% to 10% (col. 7, lines 18-22). Thus, the amount of pomegranate extract (of Lansky) is in sufficient amounts to neutralize free radicals. Cocoa butter and beeswax of Lansky read on the hydrophobic moisturizing agents and hydrophilic lanolin (col. (col. 7, line 3) read on hydrophilic moisturizing agents. Lansky does not teach the claimed hydrophilic and hydrophobic moisturizing agents; manganese, copper or selenium components and other extracts, sunscreens of the instant claims.

Crotty teaches skin care compositions containing fruit extracts, zinc salts and other components such as ceramides, vitamins, mono- or polyhydroxy acids etc. See abstract, col. 4, lines 15-22 and col. 5, lines 12-40. In particular, Crotty teaches N-acetyl cysteine, which meets the requirement of instant cysteine component (col. 4, lines 10-14). Crotty teaches fruit extracts such as grape fruit, strawberry, vanilla fruit, blackberry fruit etc., as anti-oxidants and free-

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radical inhibitors (col. 3). Further, Crotty teaches herbal extracts for sebum/oil control include wheat (col. 4, lines 15-20), which reads on hydrophilic moisturizing agent and ceramides (abstract) as well as tocopherol linoleate (col. 4, lines 2-3). Crotty also teaches plant extracts such as rosemary, soy, Echinacea, ginkgo etc., phytoestrogens, herbal extracts, alpha- and beta-hydroxycarboxylic acids, anti-inflammatory, vitamins, flavonoids etc., all of which read on the claimed moisturizers, sunscreens, transition metals, anti-inflammatory agents, immunity boosting agents, ceramides, zinc salts etc. See col. 2, lines 40 through col. 5, lines 43, for individual vitamins, hydroxycarboxylic acids, plant or herbal extracts and other components. Crotty suggests adding phytoestrogens in their skin care compositions because of their antioxidant or free radical inhibiting activity. See table in col. 3. However, Crotty fails to teach pomegranate extract, manganese, copper and selenium of the instant claims.

Thornfeldt teaches compositions and methods for preventing and reversing signs and symptoms of intrinsic and photo aging comprising pyridine-thiol and tautomers with attached metallic moiety and a metallic sulfide or oxide. Thornfeldt teaches antioxidants such as selenium as an immunomodulator, which acts by binding the key detoxification/antioxidant enzyme glutathione peroxidase (col. 2, lines 56-58). Thornfeldt also teaches that multiple metallic ion cofactors are needed as catalysts and teaches adding metal ions such as copper, manganese, selenium etc., in the anti-aging composition (col. 3, lines 40 through col. 4, lines 9). Thus metal complexed (in particular, manganese, copper, selenium) pyridine thiols of Thornfeldt read on the instant manganese component, copper component and selenium component. Further, Thornfeldt teaches metallic oxides such as zinc oxides (col. 4, lines 17-21), polyhydroxy acids, catechins, anti-inflammatory agents, vitamins, plant extracts etc (col. 6, lines 33 through col. 7, lines 9).

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It would have been obvious for one of an ordinary skill in the art at the time of the instant invention that the phytoestrogens of Lansky while supplementing estrogens also acts as antioxidants to inhibit free radicals because Crotty teaches that phytoestrogens are a suitable source of antioxidants. Accordingly, it would have been obvious for one of ordinary skill in the art to use the composition of Lansky for treating various skin conditions to provide antioxidant activity and also add to add various herbal/plant extracts, antioxidants, hydroxycarboxylic acids, anti-inflammatories etc., of Crotty, with an expectation to achieve the art recognized effect taught by Crotty i.e., anti-inflammatory effect, antioxidant, moisturizing, antimicrobial effect etc.

Further, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to modify the teachings of Lansky so as to incorporate manganese, copper or selenium complexes of pyridine thiols and zinc oxide of Thornfeldt in the composition of Lansky because Thornfeldt teaches that the metallic ion complexed pyridine thiols are effective in preventing the symptoms and signs of aging by selectively acting as cofactors for antioxidant enzymes. Accordingly, a skilled artisan would have expected to see an enhanced antioxidant effect with the phytoestrogens from pomegranate extracts as well as the metallic catalysts (metal complexed pyridine thiols).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
August 30, 2002

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600